UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,589	01/18/2002	Dianne M. Perez	26473/04200	4045

24024 7590 10/04/2005

CALFEE HALTER & GRISWOLD, LLP
800 SUPERIOR AVENUE
SUITE 1400
CLEVELAND, OH 44114

EXAMINER	
FALK, ANNE MARIE	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/052,589	PEREZ ET AL.	
	Examiner	Art Unit	
	Anne-Marie Falk, Ph.D.	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17 and 22-39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 22-39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 July 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/02, 4/02,& 8/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The proposed drawing changes to Figures 1 and 2, filed July 5, 2005, are approved. The replacement drawings filed July 5, 2005 have been entered.

The amendment filed March 7, 2005 has been entered. Claim 17 has been amended. Claims 18-21 have been cancelled. Claims 22-39 have been newly added.

The amendment to the specification filed November 12, 2004 has been entered. The claim amendments filed November 12, 2004 were not entered for reasons of record.

The remarks filed November 12, 2004 (hereinafter referred to as "the response") are considered herein.

Claims 17 and 22-39 are pending in the instant application.

The objection to the specification for new matter as set forth in the prior Office Action is withdrawn. However, additional issues of new matter were raised by the amendment to the specification filed on November 12, 2004, as set forth herein below.

The rejection of the claims under 35 U.S.C. 112, first paragraph, for failing to comply with the written description requirement, is withdrawn in view of the amendments to the claims.

The rejections of the claims under 35 U.S.C. 112, second paragraph, for indefiniteness, are withdrawn in view of the amendments to the claims and the cancellation of Claims 18-21. However, a further rejection under 35 U.S.C. 112, second paragraph, is set forth below, necessitated by Applicants' amendment.

Specification

The disclosure is objected to because of the following issue:

The disclosure uses the terms W1, W2, S1, T1, and T2, but does not explain what these terms mean. Thus, it is unclear what W2, S1, T1, and T2 mice are and it is impossible to determine what the specification is attempting to teach by use of these mice. See, for example, the specification at page 3, line 27, page 4, lines 5, 12, 13, 16, and 24-26, and page 17, lines 3, 4, and 5, and throughout the specification.

Appropriate correction is required.

New Matter in Specification

The amendment filed November 12, 2004 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The amendment presented at page 2 of the paper filed November 12, 2004 includes new matter. The specification has been amended at page 3, line 22, so that it now provides an explanation for the W1, W2, S1, T1, and T2 terminology used throughout the specification. However, such added material constitutes new matter and Applicant has not pointed to any support for the newly added material in the application as-filed.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Enablement

Claim 17 stands rejected and Claims 22-39 are rejected under 35 U.S.C. 112, first paragraph, for reasons of record, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

At page 9, paragraph 4 of the response, Applicants state that Claim 17 has been amended to recite that the claim is directed to treating a subject with a Parkinsonian type neurodegenerative disorder and has been further amended to recite a step of administering an α_{1B} adrenergic receptor antagonist to the subject. Applicants point to Example 3 for showing that a transgenic animal exhibiting Parkinsonian type symptoms and enzyme deficiencies were treated with terazosin, which reduced the apparent symptoms. Applicants further state that the specification provides a list of antagonists known in the art.

First, Applicants are reminded that the written description requirement is severable from the enablement requirement. *In re Barker*, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), *cert.* denied, 434 U.S. 1064 (1978); *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) (While acknowledging that some of its cases concerning the written description requirement and the enablement requirement are confusing, the Federal Circuit reaffirmed that under 35 U.S.C. 112, first paragraph, the written description requirement is separate and distinct from the enablement requirement and gave an example thereof). An invention may be described without the disclosure being enabling (e.g., a chemical compound for which there is no disclosed or apparent method of making), and a disclosure could be enabling without describing the invention (e.g., a specification describing a method of making and using a paint composition made of functionally defined ingredients within broad ranges would be enabling for formulations falling within the description but would not describe any specific formulation). See *In re Armbruster*, 512 F.2d 676, 677, 185 USPQ 152, 153 (CCPA 1975).

Thus, a description of various antagonists that could be used in a treatment method is not sufficient to enable the method of treatment.

Second, it is noted that the enablement rejection points out that art-accepted disease models are not exemplified. The transgenic mouse used in the experiments of Example 3 is not an art-accepted model for Parkinson's disease, epilepsy, or a tyrosine hydroxylase deficience disorder. Thus, the specification fails to provide a working example for the treatment of a neurodegenerative disease, as art-accepted disease models are not exemplified. Further, the rejection points out the unpredictability in the art and the very broad scope of the claims with regard to the various types of neurodegenerative disorders covered by the claims. While the claims have been narrowed somewhat in terms of the types of neurodegenerative diseases, no scope of enablement has been indicated for the claimed invention, for reasons of record.

Given the limited examples, the limited guidance provided in the specification, the lack of any showing of therapeutic benefit upon *in vivo* administration of a compound as recited in the claims in an art-accepted disease model, the broad scope of the claims, and the unpredictability for producing a therapeutic effect upon administration of a compound as recited in the claims, undue experimentation would have been required for one skilled in the art to develop a protocol within the scope of the claims for treating a wide variety of neurodegenerative diseases.

No further arguments have been offered with regard to this rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17 and 22-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 22-34 are indefinite in their recitation of "a Parkinsonian-type neurodegenerative disorder" because the metes and bounds of this term are not clearly set forth in the specification.

Conclusion

No claims are allowable.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne-Marie Falk whose telephone number is (571) 272-0728. The examiner can normally be reached Monday through Friday from 10:30 AM to 7:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The central official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Anne-Marie Falk, Ph.D.

Anne-Marie Falk

ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER